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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Moxidectin Gel

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Fort Dodge Animal Health. The supplemental NADA provides for oral use of moxidectin gel for horses and ponies for treatment and control of *Gasterophilus nasalis* (3rd instars) infections.

EFFECTIVE DATE: ***(Insert date** of publication **in the*** **Federal Register.)**

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7543.

SUPPLEMENTARY INFORMATION: Fort Dodge Animal Health, Div. of American Home Products Corp., 800 5th St. NW, P.O. Box 518, Fort Dodge, IA 50501, filed supplemental NADA 141-087 that provides for use of Quest™ moxidectin 2-percent equine oral gel in horses and ponies for treatment and control of horse stomach bot ***G. nasalis*** (3rd instars). The product is approved for treatment and control of infections of certain large strongyles, small strongyles (adult and larvae), encysted cyathostomes, ascarids, pinworms, hairworms, large-mouth stomach worms, and horse stomach bots ***(G. intestinalis*** (2nd and 3rd instars)), and for suppression of strongyle egg production for 84 days. The supplemental NADA is approved as of October 4, 1999, and the regulations are amended in 21 CFR 520.1452(d)(2) to reflect the approval. The basis for approval is discussed in the freedom of information summary.

Also, § 520.1452 is amended in paragraph (d)(2) to state that the drug will suppress strongyle egg production for 84 days, and paragraph (d)(3) is amended to remove statements required elsewhere by the regulations or not required to be codified.

In accordance with the freedom of information provisions of 21 CFR part 20 and 5 14.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday, except on Federal holidays.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act, this approval for nonfood producing animals qualifies for 3 years of marketing exclusivity beginning October 4, 1999, because the application contains substantial evidence of the effectiveness of the drug involved or any studies of animal safety required for approval of the application and conducted or sponsored by the applicant. The 3 years of marketing exclusivity applies only to use for treatment and control of horse stomach bot G. *nasalis (3rd instars) infections.*

FDA has determined under 21 CFR 25.33(d) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

List of Subjects in 21 CFR Part 520

Animal drugs.

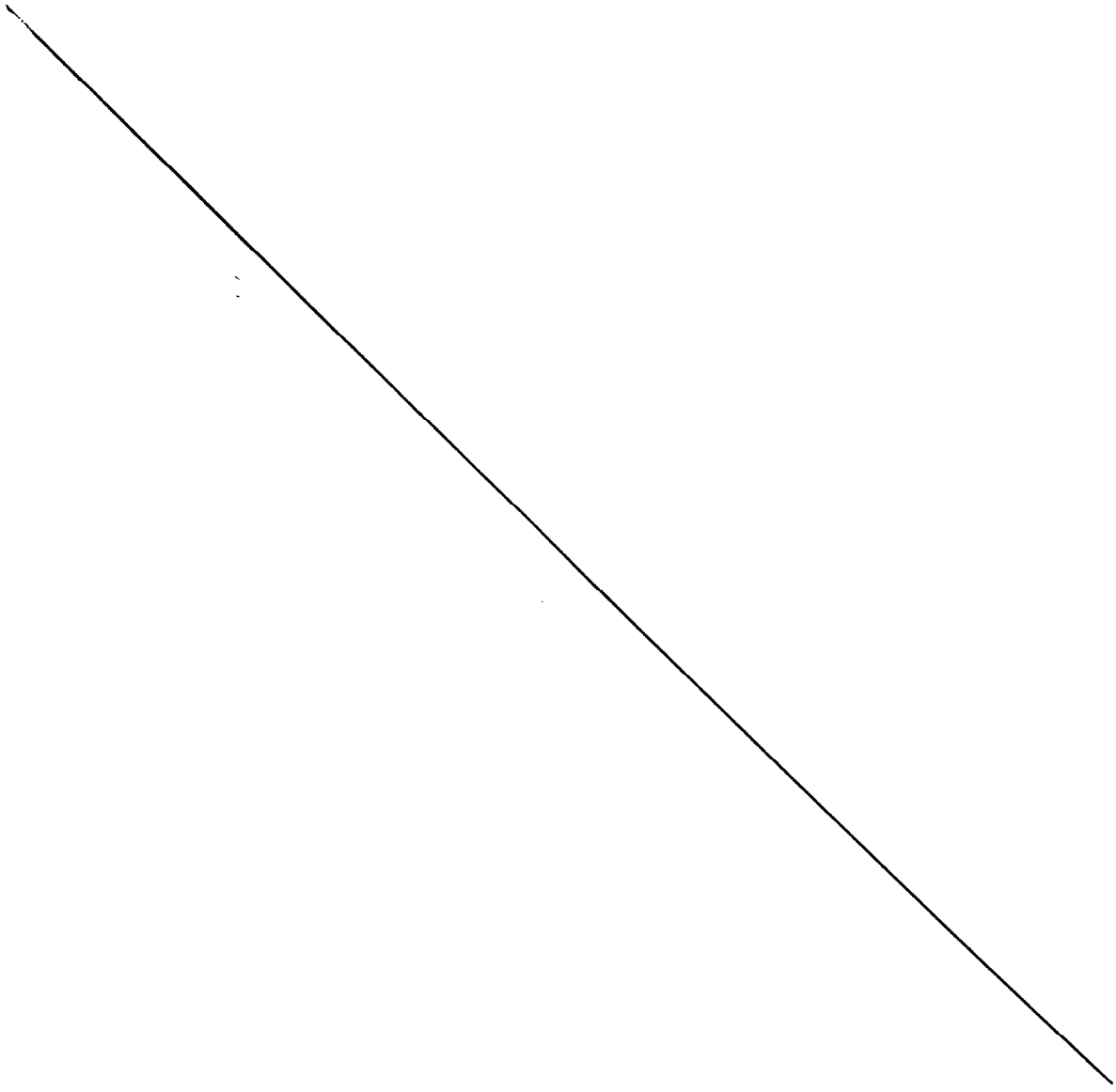
Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

PART 520-ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 2 1 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

2. Section 520.1452 is amended in by revising paragraph (d)(2) and (d)(3) to read as follows:



§ 520.1452 Moxidectin gel.

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(d) * * *

(2) Indications for use. Horses and ponies for treatment and control of large strongyles (*Strongylus vulgaris* (adults and L4/L5 arterial stages), S. ***edentatus*** (adult and tissue stages), ***Triodontophorus brevicauda*** (adults), ***T. serratus*** (adults)); small strongyles ***(Cyathostomum*** spp. (adults), *Cylicocyclus* spp. (adults), *Cylicostephanus* spp. (adults), *Gyalocephalus* ***capitatus*** (adults), undifferentiated lumenal larvae); encysted cyathostomes (late L3 and L4 mucosal cyathostome larvae); ascarids (*Parascaris equorum* (adults and L4 larval stages)); pinworms (*Oxyuris* ***equi*** (adults and L4 larval stages)); hairworms ***(Trichostrongylus*** *axei* (adults)); large-mouth stomach ***worms (Habronema*** *muscae* (adults)); and horse stomach bots ***(Gasterophilus intestinalis*** (2nd and

3rd instars) and G. *nasalis* (3rd instars)). One dose also suppresses strongyle egg production for ***84*** days.

(3) Limitations. Not for use in horses and ponies intended for food.

Dated: 11-12-9
November 12, 1999

Melanie R. Berson
Acting Director
Office of New Animal Drug Evaluation
Center for Veterinary Medicine

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